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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,112	01/25/2002	Kurt Osher	45579/56876	1887
21874	7590	07/25/2005	EXAMINER	
EDWARDS & ANGELL, LLP			MILLER, CHERYL L	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
			3738	

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tata

Office Action Summary	Application No.	Applicant(s)	
	10/057,112	OSTHER ET AL	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32, 40-42 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-32, 40-42 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 29-33, 39-42 and 52 have been considered but are moot in view of the new ground(s) of rejection. However, since some of the rejections previously applied have been maintained, the examiner has responded to the corresponding arguments.

The applicant argued the Athanasiou reference, however did not mention what the reference lacked with respect to claim 52. This rejection has been maintained.

The applicant argued that the Schwartz reference disclosed a film instead of a membrane. The examiner disagrees with the applicant. Membrane, by its broadest definition, means a thin flexible sheet or layer. Therefore, a film may be considered a membrane. Even so, Schwartz's insert 16, need not be a porous film, but instead may be a sponge matrix, shown as a membrane in the figures. Schwartz's "film" he refers to, is 22 seen in the figures, not insert 16. And insert 16, is disclosed to be made of collagen I, col.10, lines 58-65. This rejection has been maintained.

The applicant argued the Kubo reference, however did not mention what the reference lacked with respect to claim 52. This rejection has been maintained.

The applicant has argued that Li does not disclose fibronectin in the active form with RGD's, however the examiner disagrees. Li discloses fibronectin in cases where drug delivery is the purpose (col.6, lines 59-61). Therefore, Li would not want to crosslink the fibronectin, if the whole point is for the drug release. Also, nowhere in the Li reference was it found to cross-link the fibronectin. Despite this argument, all claimed components are present in the Li reference. This rejection has been maintained.

Information Disclosure Statement

The information disclosure statement filed May 2, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible **copy** of each cited foreign patent document; each **non-patent literature publication** or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 52 is rejected under 35 U.S.C. 102(e) as being anticipated by Athanasiou et al. (USPN 5,876,452, cited by applicant in IDS). Athanasiou discloses a cartilage membrane (implant) and kit comprising at least one surface part carrying a composition (bioactive agent) comprising at least one stimulation molecule; which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins, proteoglycans, and non-collagenous proteins (col.9, lines 28-49).

Claims 29-32, 40-42, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al. (USPN 6,251,143 B1, cited in previous office action). Schwartz discloses a porous cartilage membrane (insert 16; col.10, lines 51-67) comprising collagen type I (col.10, lines 58-65) and kit comprising at least one surface part carrying a composition comprising at least one stimulation molecule (attachment factor, RGD sequence, fibronectin; col.4, lines 16-26; col.11, lines 8-20), which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins, proteoglycans, and non-collagenous proteins (fibronectin being a non-collagenous protein for example).

Claim 52 is rejected under 35 U.S.C. 102(b) as being anticipated by Kubo et al. (US 5,236,447, cited previously). Kubo discloses a kit (fig.1, 10) comprising a membrane (10; that could be used for cartilage, this is intended use language, and Kubo's membrane is capable of functional at that location) comprising at least one surface part carrying a composition selected from the group consisting of collagen proteins, non-collagen proteins, or proteoglycans (composition, col.3, lines 59-65; col.7, lines 51-55).

Claims 29-32, 40-42, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Li (US 5,206,028). Li discloses a membrane and kit (which may be used for any medical application, col.5, lines 28-42) comprising a type I collagen membrane (membrane matrix, col.1, lines 7-9; col.3, lines 60-61; col.5, lines 59-63) comprising at least one surface part carrying a composition (additive, col.6, lines 59-68) having a stimulation molecule selected from the group consisting of collagen proteins, non-collagen proteins, or proteoglycans (Li discloses a

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stimulation molecule comprising proteins, proteoglycans, and fibronectin, which has an RGD motif, see col.6, lines 59-69).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is **571 273-8300**.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER